

**ER/DL SPL Team Meeting
Minutes - December 8, 2010**

Chair of today's meeting: Jessica Dunn-Skorupski

Next scheduled meeting: Jan 5, 2011

Teleconference numbers:

Telephone number: 866-217-3840

Access code: 897 2163

Topics discussed

1. Relabeler and Repackager of a branded product. The SPL is posted on the DailyMed using the approved branded products Content of Labeling but Jpegs and drug listing (different NDC from the approved branded product) of the Relabeler or Repackager. – Marilyn (BI)
 - a. This is the usual process for repackers. They use the SPL of the source company, modify the How Supplied section and DLDE information (using the source NDC code), and use their own PDP section.
 - b. There is a Q&A about repacking available on the SPL wiki – search for “repack”. The information originated with a conversation with FDA about re-packing.
 - c. More information from a repacker: Some companies change the How Supplied section and some companies don't. FDA accepts either -- without rechecking the COL carefully.
2. DRLS overwrote one SPL when a second SPL was submitted (two different setIDs) where the same NDC product codes existed in the two different SPL files- with four NDC numbers differing in the package types. Two NDC numbers in the originally posted SPL file were removed from the NDC Directory when the second SPL file (with a different setID) was submitted. - Jean.
 - a. They eventually had a teleconference with DRLS to resolve the issue. In the teleconference, they discovered that DRLS does a manual review of each SPL. They questions situations where there are multiple SPL files.
3. A new R4 file was drug listed in October. They later sent in a revision and received an error message that picked up something from an old R3 SPL version. Somehow the validation system goes back to previous versions.
 - a. Question sent to Lonnie as to why this was happening.
 - b. This has also happened to other sponsors.
4. Is there an easy way to download an SPL file from DailyMed in XML view? – Jean
 - a. Download the label. You will get a zip file. Open the zip file and extract the xml file.
5. For your interest, the OTC sub-team will be hosting a meeting with FDA on Monday, December 13 at 1:00 pm ET. Dial **888-557-8511**, Enter Access Code **522260**, Call 202-429-9260 if there are problems accessing the teleconference. Lonnie Smith and Huascar Batista (Importation) will be the FDA guests, addressing product listing and importation issues. The OTC team will start with the questions previously submitted to Lonnie and Huascar and then move to an open Q&A
 - a.

In Process topics:

- Arranging a discussion at a future meeting with someone at CMS -- to discuss how CMS interacts with drug listing (Pat and Terry)
- Terry created a space on wiki to collect questions for future discussions with FDA: DRLS and SPL.
- Process for export products (Pat/Jean)
- Rationale for why it is difficult to have R3s removed manually from Daily Med (Howard/Jean/Pat)
- Communicating with FDA about validation errors – that result in issues with import, not being able to be compliant with instructions in approval letters, etc. (Warren, Jean, Dragan, and Jessica)